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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/073,596 | 05/06/98 | STEINMAN | 2016400005 |

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HM12/0623

| EXAMINER |
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| SCHWADRON, R |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1644 | 4 |

DATE MAILED: 06/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/073,596

Applicant(s)
Steinman et al.

Examiner
Ron Schwadron, Ph.D.

Group Art Unit
1644



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 82-100 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 82-100 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Supervisory Patent Examiner Christina Chan, at 703-308-3973. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 82-97,99 are drawn to a composition of dendritic cells, classified in Class 424, subclass 93.71
 - II. Claim 98 is drawn to a mixed culture, classified in Class 424, subclass 93.3.
 - IV. Claim 100 is drawn to an antigen, classified in Class 424, subclass 184.1.
3. Inventions I,II and III are different products. These products are structurally and functionally distinct and have different uses. Inventions I and II are drawn to cells, wherein invention III is drawn to an antigen (eg. a peptide derived from a protein). Invention I is drawn to a homogenous mixture of cells, while invention II is drawn to a mixture of two different cell types. Therefore they are novel and unobvious in view of each other and are patentably distinct.
4. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.
5. If applicant elects Group I, the following species elections are required. This application contains claims directed to the following patentably distinct species of the claimed invention.
 - A) dendritic cell precursor obtained from blood (claim 85)
 - B) dendritic cell precursor obtained from bone marrow (claim 86).

Blood and bone marrow are different tissues with different components and physiology.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 82 is generic.

6. If applicant elects Group I, the following species elections are required. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) dendritic cell precursor pulsed with self-protein (claim 93, 87, 88)
- B) dendritic cell precursor pulsed with autoantigen (claim 93)
- C) dendritic cell precursor pulsed with microorganism (claims 89,90,94,95)

The aforementioned are different antigens derived from different sources

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 82 and 83 are generic.

7. If applicant elects Group A from the previous paragraph, the following species elections are required. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) dendritic cell pulsed in vitro with tumor antigen (claim 87)
- B) dendritic cell pulsed in vitro with immunoglobulin antigen (claim 88)

The aforementioned are different antigens derived from different sources

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 82 and 83 are generic.

8. If applicant elects Group C from the previous paragraph, the following species elections are required. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) dendritic cell pulsed in vitro with virus antigen (claim 90)
- B) dendritic cell pulsed in vitro with mycobacteria antigen (claims 94,95)

The aforementioned are different antigens derived from different sources

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 82 and 83 are generic.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are

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unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600



Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

June ~~10~~, 1999

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RESTRICTION ELECTION FACSIMILE TRANSMISSION

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